If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.


(e) Designation of drugs or devices by established names

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

(a) False or misleading label

If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity exercising its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 355 of this title or under section 262(a) of title 42 for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 355(a) of this title or in section 262(a) of title 42 shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term “health care economic information” means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.

(b) Package form; contents of label

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

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may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subparagraph (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term “established name”, with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 358 of this title, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopoeia and in the Homoeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homoeopathic drug, in which case the official title used in the Homoeopathic Pharmacopoeia shall apply.

(4) As used in subparagraph (2), the term “established name” with respect to a device means (A) the applicable official name of the device designated pursuant to section 358 of this title, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopoeia and in the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not those of the United States Pharmacopoeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(g) Representations as recognized drug; packing and labeling; inconsistent requirements for designation of drug

If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not those of the United States Pharmacopoeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) Deteriorative drugs; packing and labeling

If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) Drug; misleading container; imitation; offer for sale under another name

(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) Health-endangering when used as prescribed

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.


(m) Color additives; packing and labeling

If it is a color additive the intended use of which is for the purpose of coloring only, unless the packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 379e of this title.
(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances

In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in paragraph (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with section 371(a) of this title, and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: “You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800–FDA–1088.”, except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 52 to 57 of title 15. This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers. In the case of an advertisement for a drug subject to section 333(b)(1) of this title presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

(o) Drugs or devices from nonregistered establishments

If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 360 of this title, if it was not included in a list required by section 360(j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(j) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires.

(p) Packaging or labeling of drugs in violation of regulations

If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

(q) Restricted devices using false or misleading advertising or used in violation of regulations

In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360(e) of this title.

(r) Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter

In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device’s established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 52 through 55 of title 15. This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title.

(s) Devices subject to performance standards not bearing requisite labeling

If it is a device subject to a performance standard established under section 360i of this title, unless it bears such labeling as may be prescribed in such performance standard.

(t) Devices for which there has been a failure or refusal to give required notification or to furnish required material or information

If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 360h of this title respecting the device, (2) to furnish any material or information required by or under section 360i of this title respecting the device, or (3) to comply with a requirement under section 360i of this title.
(u) Identification of manufacturer

(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

(2) If the original device or an attachment thereto does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, a reprocessed device may satisfy the requirements of paragraph (1) through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.

(v) Reprocessed single-use devices

If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement “Reprocessed device for single use. Reprocessed by ...” The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

(w) New animal drugs

If it is a new animal drug—

(1) that is conditionally approved under section 360ccc of this title and its labeling does not conform with the approved application or section 360ccc(f)(1)(A) of this title; or

(2) that is indexed under section 360ccc of this title and its labeling does not conform with the index listing under section 360ccc–1(e) of this title or 360ccc–1(h) of this title, or that has not been indexed under section 360ccc–1 of this title and its label bears the statement set forth in section 360ccc(f)(1)(A) of this title;

(x) Nonprescription drugs

If it is a nonprescription drug (as defined in section 379aa of this title that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in section 379aa of this title) may receive a report of a serious adverse event (as defined in section 379aa of this title) with such drug.

(y) Drugs subject to approved risk evaluation and mitigation strategy

If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 355(p) of this title and the responsible person (as such term is used in section 355–1 of this title) fails to comply with a requirement of such strategy for provided for under subsection (d), (e), or (f) of section 355–1 of this title.

(z) Postmarket studies and clinical trials; new safety information in labeling

If it is a drug, and the responsible person (as such term is used in section 355(o) of this title) is in violation of a requirement established under paragraph (3) (relating to postmarket studies and clinical trials) or paragraph (4) (relating to labeling) of section 355(o) of this title with respect to such drug.

(3) If it is a nonprescription drug (as defined in section 379aa of this title) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in section 379aa of this title) may receive a report of a serious adverse event (as defined in section 379aa of this title).
manufacturer affords health care facilities the opportunity for "requirements of law and, that the manufacturer affords such users the opportunity", and struck out "the health care facility" after "promptly provides!"


1997—Par. (a). Pub. L. 105–115, §114(a), inserted at end "Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to a designation approved under section 356 of this title or under section 262(a) of title 42 for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 356(a) of this title, or in section 262(a) of title 42 shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention."

Par. (d). Pub. L. 105–115, §125(b), struck out par. (d) which read as follows: "If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbonbrom, chloral, cocoa, cocaine, codeine, heroin, marihuana, morphine, opium, para-chloral, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement 'Warning—May be habit forming.'"

Par. (e)(1). Pub. L. 105–115, §412(c), amended subpart. (1) generally. Prior to amendment, subpar. (1) read as follows: "If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (3)) of the drug, if such there be, and (ii) in case it is fabricated from two or more ingredients, the established name and quantity or proportion of any bromides, ether, chloroform, acetone, acetone, hyoscine, hyoscyamine, arsenic, digitals, digitalis glucosides, mercury ouabain strophanthin, strychnine, thyroid, or any derivative or preparation thereof, contained therein; Provided, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used therefor on any proprietary name or designation for such drug or ingredient: Provided, That to the extent that compliance with the requirements of clause (A)(i) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

Par. (k). Pub. L. 105–115, §125(a)(2)(B), struck out par. (k) which read as follows: 'If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of narcotic, streptomycin, chlorotetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 356 of this title, and (2) such certificate or release is in effect with respect to such drug: Provided, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 357(c) or (d) of this title.'

1993—Par. (e)(3). Pub. L. 103–80, §3(m)(1), substituted "of such ingredient, except that": for "of such ingredient: Provided, That'."

Par. (t). Pub. L. 103–80, §3(m)(2), substituted "users, except that where": for "users: Provided, That where'."

Par. (g). Pub. L. 103–80, §3(m)(3), substituted "prescribed therein. The method for 'prescribed therein: Provided, That the method not except that": for "Pharmacopoeia: Provided further, That'."

1992—Par. (m). Pub. L. 102–571 substituted "376'": for "376'."


Par. (t). Pub. L. 94–295, §5(b)(2), substituted "doseage or manner," for "doseage, ." 1973—Par. (m). Pub. L. 94–295, §5(b)(2), substituted "the intended use of which is for" for "the intended use of which in or on drugs is for'."

Par. (e). Pub. L. 94–295, §4(b)(2), substituted "If it was manufactured" for "If it is a drug and was manufactured" and inserted ", if it was not included in a list required by section 360(i) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires'."

Pars. (q) to (t). Pub. L. 94–295, §3(e)(1), added pars. (q) to (t).

is the label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name as defined in subparagraph (2) of this subsection), of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quality or proportion for "and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name" and "the established name" or the chemical formula), (i) the established name of a drug on a label is to be printed prominently and in type at least half as large as used for any proprietary designation, and added subpar. (2) defining "established name".

Par. (g). Pub. L. 87-781, §761, 312(b), provided that if there is an inconsistency between the provisions of this par. and those of par. (e), as to the name of a drug, the requirements of par. (e) should prevail.

Par. (n). Pub. L. 87-781, §313(a), added par. (n).

1947—Par. (l). Act Mar. 10, 1947, inserted "or streptomycin" after "penicillin".
Par. (k). Act Dec. 22, 1941, added par. (k).
Par. (d). Act June 26, 1939, substituted "name, and quality or proportion" for "name, quantity, and percentage".

Effective Date of 2007 Amendment

Effective Date of 2006 Amendment
Pub. L. 109-462, §2(22)(c), (d), Dec. 22, 2006, 120 Stat. 441, provided that: 

"(1) In general.—Except as provided in paragraph (2), the amendments made by this section [enacting section 379aa of this title and amending this section and section 333 of this title] shall take effect 1 year after the date of enactment of this Act [Dec. 22, 2006]."

"(2) Misbranding.—Section 502(x) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(x)] (as added by section 333 of this title) shall apply to any nonprescription drug (as defined in such section 502(x)) labeled on or after the date that is 1 year after the date of enactment of this Act [Dec. 22, 2006]."

Effective Date of 2002 Amendment

"(1) shall be effective—

"(A) with respect to devices described under paragraph (1) of such section, 12 months after the date of enactment of the Medical Device User Fee Stabilization Act of 2005 [Aug. 1, 2005], or the date on which the original device first bears the name of the manufacturer of the original device, a generally recognized abbreviation of such name, a unique and generally recognized symbol identifying such manufacturer, whichever is later; and

"(B) with respect to devices described under paragraph (2) of such section 502(u), 12 months after such date of enactment; and

"(2) shall apply only to devices reprocessed and introduced or delivered for introduction in interstate commerce after such applicable effective date."

Pub. L. 107-250, title III, §302(a)(2), Oct. 26, 2002, 116 Stat. 1616, provided that: "The amendment made by paragraph (1) [amending this section] takes effect 15 months after the date of the enactment of this Act [Oct. 26, 2002], and only applies to devices introduced or delivered for introduction into interstate commerce after such effective date."

Effective Date of 1997 Amendment
Amendment by sections 114(a), 128(b), and 412(c) of Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of this title.

Effective Date of 1978 Amendment
Amendment by Pub. L. 95-633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95-633, set out as an Effective Date note under section 801a of this title.

Effective Date of 1970 Amendment
Amendment by Pub. L. 91-601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date established by regulations published in Federal Register, see section 8 of Pub. L. 91-601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

Effective Date of 1968 Amendment
Amendment by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

Effective Date of 1962 Amendment
Section 112(c) of Pub. L. 87-781 provided that: "This section [amending this section] shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted [October 1962]."

Section 131(b) of Pub. L. 87-781 provided that: "No drug which was being commercially distributed prior to the date of enactment of this Act [Oct. 10, 1962] shall be deemed to be misbranded under paragraph (n) of section 502 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(n)], as added by this section, until the earlier of the following dates: (1) the first day of the seventh month following the month in which this Act is enacted; or (2) the effective date of regulations first issued under clause (3) of such paragraph (n) in accordance with the procedure specified in section 701(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(e)]."

Amendment by Pub. L. 87-781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87-781, set out as a note under section 321 of this title.

Effective Date of 1960 Amendment

Effective Date: Postponement

Par. (b) and (d) to (h) effective Jan. 1, 1940, and such paragraphs effective July 1, 1940, as provided by regulations for certain lithographed labeling and containers bearing certain labeling, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date: Postponement in Certain Cases note under section 301 of this title.
transferred to restrict the existing authorities of the subsection (a) that the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers.

(b) Review and Consultation.—In making the determination under subsection (a), the Secretary shall review all available scientific evidence and research on decisionmaking and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health.

c) Report.—Not later than 1 year after the date of enactment of this Act [Mar. 23, 2010], the Secretary shall submit to Congress a report that provides:

(1) the determination by the Secretary under subsection (a); and

(2) the reasoning and analysis underlying that determination.

(d) Authority.—If the Secretary determines under subsection (a) that the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers, then the Secretary, not later than 3 years after the date of submission of the report under subsection (c), shall promulgate proposed regulations as necessary to implement such format.

e) Clarification.—Nothing in this section shall be construed to restrict the existing authorities of the Secretary with respect to benefit and risk information.

GUIDANCE; MISBRANDED DEVICES

Pub. L. 109–43, § 2(c)(2), Aug. 1, 2005, 119 Stat. 441, provided that: "Not later than 180 days after the date of enactment of this Act [Aug. 1, 2005], the Secretary of Health and Human Services shall issue guidance to identify circumstances in which the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, is not "prominent and conspicuous," as used in section 502(u) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(u)] (as amended by paragraph (1))."

§ 353. Exemptions and consideration for certain drugs, devices, and biological products

(a) Regulations for goods to be processed, labeled, or repackaged elsewhere

The Secretary is directed to promulgate regulations exempting from any labeling or packag-